

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Lisa M. Donnelly et al.
Application No:	10/608,899, Conf. # 7787
Filing Date:	June 27, 2003
Entitled:	<b>FLEXIBLE TIBIAL SHEATH</b>
Atty. Docket No:	22956-218

Group Art Unit: 3738

Examiner: Javier G. Blanco

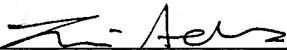
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May 22, 2007

Date

By:

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MS Amendment  
Commissioner for Patents  
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COMMENTS FOR PRE-APPEAL BRIEF REVIEW

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal, and a Pre-Appeal Brief Request for Review. A clean version of the *Pending Claims* is attached hereto.

**REMARKS**

Claims 1-9, 11-17, 20 and 21 are pending and stand rejected.

***Rejections Pursuant to 35 U.S.C. §102****U.S. Patent 5,906,632 of Bolton*

Claims 1-3, 6, 7, 11-14, 16, 17, 20, and 21 stand rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,906,632 of Bolton ("Bolton").

**Claims 1-9**

The pending rejection is deficient because the Examiner has not established that the claimed invention is anticipated by Bolton. To anticipate a claim, a reference must teach each and every element of the claim. Bolton fails to teach or even suggest an expandable sheath having a slot-free

distal tip and at least two sidewalls that have a substantially concave outer surface and that are at least partially separated by a longitudinally oriented opening that extends from a proximal end and terminates at a position just proximal to the distal tip, as required by independent claim 1.

Bolton discloses a deformable ring (20) and a screw (40) that is insertable through a cutout (220, 221) in the ring (20) to urge the ring (20) against an inner surface of a bone tunnel. First, the Examiner asserts that tip/point 222 forms a slot-free distal tip. Point 222 on the ring (20) is not slot-free. To the contrary, point 222 includes an opening or slot (220) formed therein. Thus, Bolton fails to teach a slot-free distal tip, as required by claim 1.

The Examiner also asserts that the grooves (210) formed in the flat sections (212, 213) of the ring (20) are equivalent to the substantially concave outer surface of the sidewalls recited in claim 1 of the present application. However, as explained in the last paragraph on page 2 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007, the plurality of grooves (210) formed in each flat section (212, 213) of Bolton's ring (20) result in a "sidewall" having an outer surface with a *series of ridges* – not a sidewall with a substantially concave outer surface, as required by claim 1.

Bolton also fails to disclose a longitudinally oriented opening that partially separates the sidewalls and that extends from a proximal end and terminates just proximal to the distal tip. The Examiner asserts that the grooves (218) formed in the inner surfaces of the flat sections (212, 213) of the ring (20) are longitudinal openings having such a configuration. Applicants refer the panel to arguments previously presented and set forth in the first full paragraph on page 3 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007 which outline that the grooves (218) are not equivalent to the openings recited in claim 1, nor do they extend from a proximal end and terminate just proximal to the distal tip. Accordingly, the Examiner has failed to establish that independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, are anticipated by Bolton. Thus, claims 1-9 represent allowable subject matter.

#### Claims 11-17 and 20-21

Independent claim 11 recites a graft fixation kit including a bioabsorbable expandable sheath and a *plurality* of sheath expanders of *varying sizes*. As explained in the last paragraph on page 3 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007, Bolton fails to disclose that expanders of varying sizes can be used with a *single* expandable sheath, as required by claim 11. Accordingly, the Examiner has failed to establish that independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, are anticipated by Bolton.

U.S. Patent 6,887,271 of Justin et al.

Claims 1-7 and 11-17 stand rejected pursuant to 35 U.S.C. §102(e) as being anticipated by or, in the alternative, pursuant to 35 U.S.C. §103(a) as obvious in view of U.S. Patent 6,887,271 of Justin et al. (“Justin”).

Claims 1-9

As with the Bolton rejection, the Justin rejection is also deficient because the Examiner has not established that Justin discloses each and every element of the claimed invention. Justin fails to teach or even suggest an expander that is adapted to deform a concave outer surface of a sheath toward a circular geometry. As explained in the second paragraph on page 4 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007, the expansion plug (21, 52, 310) and fixation member (20) taught by Justin are configured such that the expansion plug (21, 52, 310) is only capable of forcing the bone engaging elements (11, 12) of the fixation member (20) and/or the graft material into contact with the bone tunnel – it is not capable of deforming the grooves (23) of the fixation member (20) toward a circular geometry, as required by claim 1. Accordingly, the Examiner has failed to establish that independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, are anticipated by Justin. Thus, claims 1-9 represent allowable subject matter.

Claims 11-17 and 20-21

As set forth in the second paragraph on page 5 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007, Justin merely discloses one size expansion plug (21) and does not teach or even suggest that plugs of varying sizes can be used with a *single* fixation member (20), as required by claim 11. Accordingly, the Examiner has failed to establish that independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, are anticipated by Justin.

***Rejections Pursuant to 35 U.S.C. §103***

WO 02/32345 of Jacobs, et al.

Claims 1-4, 8, 9, 11-14, 20, and 21 stand rejected pursuant to 35 U.S.C. §103(a) as being obvious over WO 02/32345 of Jacobs, et al. (“Jacobs”). The Examiner asserts that Jacobs teaches the claimed invention except for a “bioabsorbable” sheath expander. The Examiner argues that it would have been obvious “to have used a biodegradable expander with the invention of Jacobs, et al., since it has been held to be within the general skill of a worker in the art to select a known material.”

Applicants refer the panel to arguments presented and set forth in the last paragraph on page 5 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007.

First, Jacobs fails to teach or even suggest a sheath expander, much less an expander that is configured to deform a concave outer surface of a sheath toward a circular geometry, as required by claim 1. As acknowledged by the Examiner on pg. 6 of the Office Action dated February 22, 2007, Jacobs does not explicitly disclose an “expander.” The Examiner asserts that the device (190) shown in FIGS. 5A-5C and the insertion tool (184) shown in FIGS. 4C and 4D of Jacobs are equivalent to the expandable sheath and sheath expander recited in claim 1. Specifically, the Examiner asserts that the insertion tool (184) is capable of deforming the external cavities (196) of the device (190) “in the direction of the circular geometry of the bone tunnel/bore.” However, it would be impossible for the insertion tool (184) to deform any part of the device (190) because the insertion tool (184) must be configured to allow the spring arms (192, 194, 198, 200) of the device to *flex inward* as the device (190) is installed in a bone tunnel. As explained on pg. 12, lines 3-12 and shown in FIG. 5C of Jacobs, “the various spring arms are pulled together when installed in a hole in the bone” to form an interference fit and secure the anchor device (190) within the bone tunnel. Thus, it would be impossible for the insertion tool (184) to act as an *expander*, as the device (190) must *contract* during installation.

Second, one having ordinary skill in the art would have no motivation to modify the insertion tool (184) of Jacobs to act as an expander. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). Not only is there is no advantage to modifying the anchor device (190) of Jacobs to include a sheath expander to *expand* the spring arms (192, 194, 198, 200) but such a modification is contrary to the teachings of Jacobs because, as explained above, the device (190) must *contract* during installation to secure the device (190) within the bone tunnel.

The Examiner further asserts that it would have been obvious “to have used a biodegradable expander with the invention of Jacobs.” However, one having ordinary skill in the art would have no motivation to make the insertion tool (184) of Jacobs out of a bioabsorbable material because the insertion tool (184) of Jacobs is not implanted. The insertion tool (184) is used merely to install the anchor device (190) and does not remain in the body after installation is complete. Moreover, bioabsorbable materials tend to be weak and are not generally suitable for insertion tools which require sufficient structural integrity.

Even further, Jacobs also fails to disclose a kit including a plurality of sheath expanders of varying sizes, as required by independent claim 11. As explained in the last full paragraph on page 6 of Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on April 23, 2007, Jacobs merely discloses one size pin (184) and does not teach or even suggest that expanders of varying sizes can be used with a *single* expandable sheath, as required by claim 11.

Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and therefore claims 1-9, 11-17, 20, and 21 distinguish over Jacobs and represent allowable subject matter.

WO 02/32345 of Jacobs, et al. and U.S. Publication 2002/0072797 of Hays, et al.

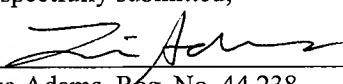
Claims 5-7 and 15-17 stand rejected pursuant to 35 U.S.C. §103(a) as being obvious over Jacobs in view of U.S. Publication 2002/0072797 of Hays, et al. ("Hays") now U.S. Patent 6,554,862. The Examiner asserts that Jacobs discloses the claimed invention except for the "stop member at a proximal end of the sheath" and "the expander as a tapered screw." The Examiner relies on Hays to teach these features arguing that it would have been obvious to combine the device of Jacobs with Hays to reach the claimed invention. As explained above, Jacobs fails to teach or even suggest a sheath expander and there is no motivation to modify Jacobs to include such a feature. Hays does not provide the requisite motivation, as an *expander* is still contrary to the teachings of Jacob which require the device (190) to *contract* during installation. Accordingly, independent claims 1 and 11, as well as claims 2-9 and 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Jacobs and Hays, taken alone or combined, and represent allowable subject matter.

***Conclusion***

In view of the above remarks, Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

Date: May 22, 2007

  
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**PENDING CLAIMS**

1. (Previously Presented) A graft fixation device for fixing a graft member within a bone tunnel, the device comprising:

a bioabsorbable radially expandable sheath having a slot-free distal tip with at least two sidewalls extending proximally therefrom and defining a central lumen, each sidewall having a substantially concave outer surface adapted to seat a graft member, and each sidewall being at least partially separated by a longitudinally oriented opening extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and

a bioabsorbable sheath expander adapted to be disposed in the central lumen of the radially expandable sheath and configured to deform the concave outer surface of the sidewalls toward a circular geometry to radially expand the sheath so as to fix the graft member within a bone tunnel.

2. (Previously Presented) The graft fixation device of claim 1, wherein the distal tip of the radially expandable sheath tapers to form a bullet-shaped distal tip.

3. (Original) The graft fixation device of claim 1, wherein the sheath expander and a distal-most end of the radially expandable sheath each include a lumen extending therethrough for receiving a guide wire.

4. (Original) The graft fixation device of claim 2, wherein the sidewalls each include surface features formed within the concave outer surface thereof.

5. (Previously Presented) The graft fixation device of claim 1, wherein at least two adjacent sidewalls of the expandable sheath are joined at a proximal end thereof by a stop member adapted to prevent over-insertion of the radially expandable sheath into a bone tunnel.

6. (Original) The graft fixation device of claim 1, wherein the sheath expander is a tapered screw.

7. (Original) The graft fixation device of claim 6, wherein the sheath expander has a largest diameter that is greater than a largest inner diameter of the radially expandable sheath in an unexpanded state.

8. (Original) The graft fixation device of claim 1, wherein the device is formed from a material having one or more polymers or copolymers formed of monomers selected from the group consisting of lactic acid, glycolic acid, and caprolactone.

9. (Original) The graft fixation device of claim 8, wherein the material further comprises tricalcium phosphate.

10. (Cancelled)

11. (Previously Presented) A graft fixation kit for fixing a graft member within a bone tunnel, the kit comprising:

a bioabsorbable expandable sheath having a proximal end and a slot-free distal tip with at least two sidewalls extending therebetween and defining a central lumen, each sidewall being at least partially separated by a longitudinally oriented opening extending from the proximal end and terminating at a position just proximal to the distal tip, and each sidewall having an outer surface adapted to seat a graft member; and

a plurality of sheath expanders of varying sizes, each being disposable in the central lumen of the expandable sheath and configured to flex the sidewalls to radially expand the sheath so as to fix at least one graft member within a bone tunnel.

12. (Previously Presented) The kit of claim 11, wherein the distal tip tapers from a distal end of each longitudinally oriented opening to a distal end of the expandable sheath.

13. (Original) The kit of claim 12, wherein the distal tip of the expandable sheath is rounded.

14. (Original) The kit of claim 12, wherein the sidewalls of the expandable sheath each include a concave outer surface having surface features formed thereon.

15. (Original) The kit of claim 11, wherein two adjacent sidewalls of the expandable sheath are joined at a proximal end thereof by a stop member adapted to prevent over-insertion of the expandable sheath into a bone tunnel.

16. (Original) The kit of claim 11, wherein each sheath expander is a tapered screw.

17. (Previously Presented) The kit of claim 16, wherein each sheath expander has a largest diameter that is greater than a largest inner diameter of the radially expandable sheath in an unexpanded state.

18-19. (Cancelled)

20. (Previously Presented) The graft fixation device of claim 1, wherein a distal-most end of the radially expandable sheath includes a bore formed therein for receiving a guide wire.

21. (Previously Presented) The kit of claim 16, wherein a distal-most end of the expandable sheath includes a bore formed therein for receiving a guide wire.

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